K103736

Jun 10 2011

DMC MEDICAL Ltd.

Unit 2, Abbey House
Shannon Town Centre
Shannon, County Clare
Ireland
353-61-7148900, Phone
353-61-7148944, Fax
TSB / Bryan Wixted
Preparation Date: April 6th 2011

Domestic Contact: Charmaine Henderson
Phone: 925-299-8702
Fax: 925-299-8702

510(K) Summary for the:

Trade Name: DMC Medical Single-Use Polycarbonate Syringe

Common Name: Syringe, Hypodermic

Classification Name: Piston Syringe, 21 CFR 880.5860, Class II Device, Product Code: FMF

Legally Marketed Predicate Devices for Substantial Equivalence:

*K070856 - ICU Medical Single-Use Syringe

Rationale for SE:

The ICU Medical Single-Use Syringe is a Class II device that is offered pre-sterilized or in bulk for offer to other kit manufacturers. The ICU Medical Single-Use Polycarbonate Syringe is made from identical materials and by the same processes.

Description of Submitted Device:

DMC Medical Single-Use Polycarbonate Syringe is offered in the same configurations as the predicate. It is made from a calibrated hollow barrel, and a moveable piston with a plunger tip at the end of the piston. The piston shaft does not contact any part of the fluid path, rather the tip which attaches to the shaft and the barrel are fluid path components. Individual components are made from properly tested materials included in this submission. Additionally, there is a small amount of lubricant for moving the piston shaft smoothly along the inside surface of the barrel. The connector is a universal luer threaded style connector. The device is used in general medicine in clinical, hospital, or other settings of healthcare professionals.

Intended Uses of the DMC Medical Syringe:

DMC Medical piston type syringes are single use syringes, intended for injecting fluids into or withdrawing fluids from the body.

Technological Characteristics and Substantial Equivalence Table:

Component:	ICU Medical, Inc.	DMC Medical, Ltd
Syringe Barrel:	Polycarbonate	Polycarbonate
Plunger Tip:	Polyisoprene	Elastomer
Silicone Oil	Medical Grade Oil	Medical Grade Oil
Calibrated Barrel Volume:	YES	YES
Sterilization method:	EtO	EtO
51 O(k) Approval	K070856	This submission

The operational characteristics, when compared to the predicate device, are identical. The user connects the syringe via the threaded luer, then manually advancing or withdrawing the plunger internal to the barrel, is able to express or withdraw fluids. Fluids are measured via the printed external housing of the barrel; measurements are indicated in ml (milliliters). Operation is similar for most all piston syringes whether fitted with a threaded luer end or a slip-fit only end.

Safety and Performance:

DMC Medical syringes conform to the requirements ofISO 7886-1, an FDA recognized standard. Additionally, the Sterility Assurance Level, (SAL) has been established to meet the 10^{-6} level. The single use syringes are packaged in a way as to ensure conformity with ISO 10993-1, including minimizing residual gases as well as discourage re-use.

Non-clinical Testing:

DMC Medical syringes are tested to ISO 7886-1, as well as pressure testing to failure. All syringes conform to ISO 10993-1, including minimizing residual gases. This testing ensures that the devices meet the needs of the healthcare professional using them. Additionally, the testing demonstrates that the device is as safe, as effective, and performs as well as or better than the predicate device.

Conclusion:

The materials, performance, and operational features of both the submitted device and the predicate device are substantially equivalent and are safe and effective for their intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

DMC Medical, Limited
C/O Ms. Tracy Best
Tracy Best Consulting
944 North Main Street
Bountiful, Utah 84010

JUN 10 2011

Re: K103736
Trade/Device Name: DMC Medical Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF
Dated: May 26, 2011
Received: June 2, 2011

Dear Ms. Best:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K103736**

Device Name: **DMC Medical Syringe**

Indications For Use: ***DMC Medical piston type syringes are single use syringes intended for injecting fluids into or withdrawing fluids from the body.***

Prescription Use ___√___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Richard C. Chapman 6/8/11

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K103736